

**REMARKS****Claim status**

Claims 1, 3-5, 8-17, 28, 30, 32, 34-35, 38-40, 42-43, 45-47, 49-52, 54-57, 59-62, and 64 were pending in the case at the time of the current Office Action. No claims are amended herein. Claims 1, 3-5, 8-17, 28, 30, 32, 34-35, 38-40, 42-43, 45-47, 49-52, 54-57, 59-62, and 64 are currently pending in the application.

**Section 103 rejections**

In the current Office action, claims 1, 3-4, 8, 40, 43, 46, 47, and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi et al. (US 6,141,585), hereinafter Prutchi, in view of Meier (EP 1,062,979 A2), hereinafter Meier. It is noted that reference to the English version of Meier (U.S. 6,522,924) is made herein.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

Independent claim 1 recites a device for delivering electrical stimulation pulses to body tissue through a stimulation electrode, comprising:

energy storage means for providing electrical stimulation energy to the stimulation electrode from an energy source;

a first switch with which the energy storage means is switchably connected to the energy source for charging the energy storage means;

an electrode connection for connecting the stimulation electrode to the device for delivering electrical stimulation pulses to the body tissue;

a second switch with which the energy storage means is switchably connected to the electrode connection for the delivery of a stimulation pulse;

means for monitoring stimulation outcome between 0 milliseconds and 10 milliseconds after said delivery of a stimulation pulse;

a short-circuit switch with which the electrode connection, after delivery of the stimulation pulse, is switchably and at least indirectly connected to a ground potential such that, in the case of a connected and implanted electrode, a capacitance can be discharged by way of the body tissue wherein the capacitance includes at least one Helmholtz capacitance produced on the surface of the stimulation electrode in conjunction with surrounding body fluid or the body tissue (emphasis added); and

a control unit which is connected to at least the first switch, the second switch, and the short-circuit switch for switching the respective switches and which is adapted to separate the electrode connection from the energy storage means after delivery of the stimulation pulse and at least indirectly connect the electrode connection to the ground potential (emphasis added);

wherein the means for monitoring stimulation outcome, between 0 milliseconds and 10 milliseconds after delivery of a stimulation pulse, is connected to the electrode connection and is adapted to detect a drop in a voltage over time at the capacitance or a rise in a short-circuit current over time at the capacitance, (emphasis added) said drop in voltage or said rise in short-circuit current being representative of a characteristic drop in a myocardium impedance of said body tissue indicating stimulation success.

The claimed invention of claim 1 is directed to a device that detects a drop in a voltage or a rise in a short-circuit current, between 0 and 10 milliseconds after the delivery of a stimulation pulse, at a capacitance that includes at least one Helmholtz capacitance produced on the surface of the stimulation electrode in conjunction with surrounding body fluid or the body tissue. The drop in voltage or the rise in short-circuit current over time is representative of a characteristic drop in a myocardium impedance over time, indicating stimulation success. With the claimed invention of claim 1, a short term drop in the impedance of the myocardium itself is detected. In order to measure such short term drop of impedance, a current or a voltage source is used which is readily available immediately after delivery of the stimulation pulse. According to the claimed

invention, a capacitor that is in the short cut circuit (from the myocardium to ground potential) during autoshort after delivery of a stimulation pulse is used as a current or a voltage source. The short term drop of myocardial impedance is detected by evaluating a time course of a voltage or a current over a capacitance in the short cut circuit. This capacitance can be a coupling capacitor 24, a Helmholtz capacitance 32, or a combination of both (see Fig. 1 of the present application), or any other capacitance in the short cut circuit as would be apparent to one skilled in the art. One skilled in the art knows that a load impedance can be determined by either analyzing a time course of a voltage when discharging a capacitor into a load, or a time course of a current, since it is the slope of the voltage or the current that characteristically depends on the load (impedance of the myocardium).

In summary, the claimed subject matter of the present application is directed to a characteristic drop in myocardial impedance that is measured during a so-called autoshort period when the stimulation electrode is short-circuited immediately after delivery of the stimulation pulse by means of the short circuit switch. A capacitor that is in the short cut circuit (from the myocardium to ground potential) during autoshort after delivery of a stimulation pulse is used as a current or a voltage source. Also, as may be seen from Figures 3 and 4 of the present application, the relevant time interval is between 0 milliseconds and 10 milliseconds after delivery of the stimulation pulse.

As stated by the Examiner, Prutchi does not disclose a means for monitoring stimulation outcome between 0 and 10 milliseconds after delivery of a stimulation pulse that is connected to an electrode connection and is adapted to detect a drop in voltage over time at the capacitance or a rise in short-circuit current over time at the capacitance, either being representative of a characteristic drop in a myocardium impedance of the body tissue indicating stimulation success. Prutchi does not disclose means for monitoring stimulation outcome in combination with the switching of a short-circuit switch. Although Prutchi discloses capacitor  $C_B$  and short-circuit switch S3 in Fig. 5 of Prutchi, Prutchi does not disclose to close switch S3 immediately after delivery of a stimulation pulse and to measure the current or voltage over capacitor  $C_B$  immediately after closing switch S3.

Furthermore, referring to Fig. 1 and Fig. 3 of Meier, Meier relies on using active measurement pulses 18 provided by the pulse generator 3 (emphasis added) as a current or voltage source for measuring myocardial impedance after delivery of a stimulation pulse 16 by that same pulse generator 3. The claimed invention of claim 1 does not rely on such active pulses to act as a voltage source or a current source in order to facilitate the measurement of myocardial impedance. Instead, in the claimed invention as described previously herein, a current or a voltage source is used which is readily available immediately after delivery of the stimulation pulse. According to the claimed invention of claim 1, a capacitor that is in the short cut circuit (from the myocardium to ground potential) during autoshort after delivery of a stimulation pulse is used as a current or a voltage source. The device of claim 1 does not rely and does not provide such active measurement pulses as does Meier. In fact, the device of claim 1 disconnects the pulse generator (energy storage means) from the electrode connection after delivery of a stimulation pulse and shorts the electrode connection to ground. This may be seen in Fig. 1 of the present application where, after delivery of a stimulation pulse, the second switch S2 is opened and the short-circuit switch S3 is closed in order to short the electrode connection to ground 16.

Therefore, using the device of Meier to modify the device of Prutchi would not result in the device of the claimed invention of claim 1 but would instead result in some other device that uses active measurement pulses after delivery of a stimulation pulse. The cleverness of the claimed invention of claim 1 is, in part, the fact that active measurement pulses do not have to be used, thus allowing for a longer operating life of the energy source 20.

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claim 1 is not unpatentable over Prutchi in view of Meier, and it is respectfully submitted that independent claim 1 defines allowable subject matter. Also, since claims 3-4, 8, 40, 43, 46, 47, and 50-52 depend either directly or indirectly from claim 1, it is respectfully submitted that claims 3-4, 8, 40, 43, 46, 47, and 50-52 define allowable subject matter as well.

Applicants respectfully request that the rejection of claims 1, 3-4, 8, 40, 43, 46, 47, and 50-52 U.S.C. 103(a) be removed.

In the current Office action, claims 5, 28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi in view of Meier as applied to claim 1 and 3-4 above, and further in view of Lewyn et al., (US 4,114,627), hereinafter Lewyn.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

As described above, it is respectfully submitted that neither Prutchi, Meier, nor the combination thereof teaches, suggests, or renders obvious the invention of independent claim 1.

Furthermore, neither Prutchi, Meier, Lewyn, nor the combination thereof teaches, suggests, or renders obvious the invention of independent claim 1.

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claim 1 is not unpatentable over Prutchi, Meier, Lewyn, nor the combination thereof, and it is respectfully submitted that independent claim 1 defines allowable subject matter. Also, since claims 5, 28, and 30 depend either directly or indirectly from claim 1, it is respectfully submitted that claims 5, 28, and 30 define allowable subject matter as well.

Applicants respectfully request that the rejection of claims 5, 28, and 30 under U.S.C. 103(a) be removed.

In the current Office action, claims 55-57 and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi in view of Meier as applied to claims 1, 40, 43, 46, 47, and 50-52 above, and further in view of Paul (US 5,713,931), hereinafter Paul.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

As described above, it is respectfully submitted that neither Prutchi, Meier, nor the combination thereof teaches, suggests, or renders obvious the invention of independent claim 1.

Furthermore, neither Prutchi, Meier, Paul, nor the combination thereof teaches, suggests, or renders obvious the invention of independent claim 1.

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claim 1 is not unpatentable over Prutchi, Meier, Paul, nor the combination thereof, and it is respectfully submitted that independent claim 1 defines allowable subject matter. Also, since claims 55-57 and 60-62 depend either directly or indirectly from claim 1, it is respectfully submitted that claims 55-57 and 60-62 define allowable subject matter as well.

Applicants respectfully request that the rejection of claims 55-57 and 60-62 under U.S.C. 103(a) be removed.

#### **Allowable Subject Matter**

In the current Office action, claims 9-17, 32, 34, 35, 38, 39, 42, 45, 49, 54, 59 and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants thank the Examiner for identifying the allowable subject matter above. However, Applicants believe that independent claim 1 is allowable in its present form and, therefore, have not re-written any of the above identified claims in independent form as suggested by the Examiner at this time.

Applicants respectfully submit that independent claim 1 defines allowable subject matter. Also, since claims 9-17, 32, 34, 35, 38, 39, 42, 45, 49, 54, 59 and 64 depend either directly or indirectly from claim 1, it is respectfully submitted that claims 9-17, 32, 34, 35, 38, 39, 42, 45, 49, 54, 59 and 64 define allowable subject matter as well.

Applicants respectfully request that the objection of claims 9-17, 32, 34, 35, 38, 39, 42, 45, 49, 54, 59 and 64 be removed and that allowance of claims 9-17, 32, 34, 35, 38, 39, 42, 45, 49, 54, 59 and 64 in their present dependent form will be forthcoming.

Accordingly, the Applicants respectfully request reconsideration of the rejections and objections based on at least the foregoing. After such reconsideration, it is urged that allowance of all pending claims will be in order.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'David J. Muzilla', written in a cursive style.

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